Siemens Medical Solutions USA, Inc.
Oncology Care Systems

K060226

MAR 15 2006

Section 5
510(k) Summary

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520

Contact: Christine Dunbar
Senior Regulatory Affairs Specialist

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Proprietary Name: ONCOR Expression™ with COHERENCE™ Workspaces

Common Name: Accelerator, Linear, Medical

Classification: 892.5050

Product Code: IYE

Substantial Equivalence Claimed To:

PRODUCT	Clearance	Claim of Equivalence For:
ONCOR Avant-Garde with COHERENCE Workspaces Includes OPTIVUE and PRIMEVIEW	K031764	ONCOR Expression linear accelerator with COHERENCE Workspaces, includes the OPTIVUE 1000ST, an Electronic Portal Imaging Device used for Portal Imaging for Image registration and Adaptive Targeting. PRIMEVIEW3i is the version for use with the PRIMUS product line.
PRIMUS	K993425	ONCOR Expression linear accelerator
LEONARDO	K040970	Syngo based applications on COHERENCE Workspaces
Siemens Siremobile Iso-C 3D Specifically 3D reconstruction application.	K040347	3D Cone Beam Reconstruction

Description Summary:

Within the submission the following internal naming conventions are used:

Market Name	Internal naming convention
ONCOR Expression	ONCOR linear accelerator and ACCEL release 2
ONCOR Avant-Garde	ONCOR linear accelerator and ACCEL release 1
PRIMUS	PRIMUS linear accelerator
PRIMEVIEW	Siemens proprietary verify and record system. The *syngo* based PRIMEVIEW is hosted on the COHERENCE Therapist Workspace. The syngo base version is marketed as PRIMEVIEW3i and is used on the PRIMUS linear accelerator systems.
COHERENCE Therapist Workspace	RTT Workspace

Market Name	Internal naming convention
COHERENCE Oncologist Workspace	MD Workspace
OPTIFOCUS	82-leaf multi-leaf collimator
OPTIVUE	aSi flat panel electronic portal imaging device (EPID) AL7 model
OPTIVUE 1000ST	aSi flat panel electronic portal imaging device (EPID) AG9 model
LEONARDO	*Syngo* based workstation
syngo	Siemens proprietary software architecture and hosting Siemens software applications organized by task cards on a dedicated workstation.

ONCOR Expression™ with COHERENCE Workspaces:
The ONCOR Expression is a medical linear accelerator based on the previously cleared ONCOR Avant-Garde (K031764) and PRIMUS (K993425) design architecture and includes as standard these features:

- New generation amorphous Silicon (aSi) flat panel electronic portal imaging device (EPID) marketed as OPTIVUE 1000ST,
- COHERENCE Therapist Workspace
- Release 2 software including MVision™ the Megavoltage Cone Beam Imaging Package
    - Megavoltage Cone Beam acquisition
    - Megavoltage Cone Beam reconstruction
        - MVCB Geometry Calibration
        - 3D Image Phantom
    - Adaptive Targeting™
- an 82 leaf multi-leaf collimator (MLC) marketed as OPTIFOCUS, and
- the patient treatment couch; 550 TxT (K050422), or the ZXT (K910971).

OPTIVUE™ 1000ST:
The previously cleared flat panel (OPTIVUE) is integrated into the linear accelerator system and aids in positioning verification by visualizing patient positioning markers and/or anatomical references. The intended use of the OPTIVUE flat panel device, cleared under K031764, remains unchanged. The upgrade to this device consists of a newer generation of aSi detector and the market name will be denoted as the OPTIVUE 1000ST.

As with the previously cleared OPTIVUE device, the OPTIVUE 1000ST flat panel device is designed to detect radiation from the linear accelerator, this information is then interpreted via software to obtain portal images for the visualization of patient positioning markers and/or anatomical structures. The original OPTIVUE device included automated deployment of the flat panel that eliminated the need for the treating therapist to enter the treatment room to acquire portal images. The OPTIVUE 1000ST flat panel is intended to fit within the original deployment hardware, however, the newer flat panel upgrade requires the Release 2 software.

Refer to Section 11 Design Description, for the Product Specification regarding the OPTIVUE 1000ST flat panel EPID.

OPTIFOCUS™:
The 82 leaf multi-leaf collimator, marketed as OPTIFOCUS and previously cleared under K031764, is integrated into the ONCOR Expression system and allows for user definable optimization of resolution for target conformation The OPTIFOCUS MLC remains unchanged in design and functionality and is unchanged from its original intended use.

***Syngo*™:**
The original COHERENCE Workspace software for Release 1 (K031764) was based on the software architecture of the previously cleared *syngo* software (K010938) and allows for a standardized graphical user interface across Siemens medical products. The *syngo*-based software design consists of task cards

allowing for a selection of modules of common software applications for image acquisition, reconstruction, post-processing, display, and archiving across the Siemens medical product lines. The latest in *syngo* software applications for the reconstruction, post- processing and display of images are included in the previously cleared workstation under the market name of LEONARDO (K040970).

As part of the Siemens Medical Solutions family of workstations, the *syngo* based workstations (Oncology Care System calls a "workstation" a "workspace") offers a configurable selection of software applications depending on the type of *syngo* package that is required for a specific modality. There are multiple applications in common across all Siemens imaging modalities as previously mentioned. In this submission, the previously cleared 3D reconstruction application module utilized on the Siemens Siremobile Iso-C 3D C-Arm product will be utilized on the COHERENCE Therapist workspace as part of the MVision feature and supports Cone Beam reconstruction.

MVision™ Megavoltage Cone Beam Imaging Package:
As an upgrade to the previously cleared COHERENCE Therapist Workspace, Release 2 introduces the new features under the market name MVision™ Megavoltage Cone Beam Imaging Package, (MVision for short). The new features consist of a new acquisition method called Megavoltage Cone Beam acquisition which acquires 2D projection data. The data is then processed using the Cone Beam reconstruction and the 3D data can be utilized by the patient localization application called Adaptive Targeting™.

Megavoltage Cone Beam Geometry Calibration is a required service installation procedure and is used in conjunction with the 3D Image Quality Phantom.

Adaptive Targeting™:
The previously cleared COHERENCE Therapist Workspace provided a *syngo* based interface for 2D, 3D, and volumetric targeting of the radiation treatment using the Portal Imaging application for the purposes of patient position localization and setup.. Improvements to the volume targeting application for advanced Image Guided Radiation Therapy (IGRT) is featured in the new Adaptive Targeting application, which supports alignment of 3D planning data with newly acquired 3D Cone Beam data for the purposes of patient position localization and setup.

PRIMEVIEW™:
The previously cleared PRIMEVIEW (K972275) Verify and Record application had been integrated into the previously cleared COHERENCE Therapist Workspace (K031764) and is selectable by the operator using the *syngo* based task card. The task card would launch the PRIMEVIEW software module. The original PRIMEVIEW V & R application continued to support the *syngo* based architecture of the PRIMUS systems and is marketed under the name PRIMEVIEW3i.The PRIMEVIEW application was updated to support the Megavoltage Cone Beam arc treatment acquisition method utilizing a very low MU dose rate. The MVCB acquisition is recorded to the patient's treatment record. The intended use of the PRIMEVIEW V & R system remains unchanged.
Note: PRIMEVIEW3i has a 510(k) Non-Filing Justification on file because the application differs only in name from the PRIMEVIEW application.on the COHERENCE Therapist workspace

Refer to Section 11 Design Description, for the design description and functional specifications of these new features.

The OPTIVUE 1000ST, OPTIFOCUS 82 leaf MLC, 550 TxT patient couch, ZXT patient couch, PRIMEVIEW3i and COHERENCE Oncologist Workspace, will also be available as individual purchased options to existing Siemens PRIMUS and ONCOR medical linear accelerator product lines.

Intended Use:

The intended use of the ONCOR Expression linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer.

The ONCOR Expression includes an Electronic Portal Imaging Device (EPID) that will be marketed as OPTIVUE 1000ST and is used for the verification of the treatment field and shielding blocks in relation to patient positioning fiduciary markers and/or anatomical landmarks in radiotherapy treatment. OPTIVUE 1000ST will also allow for verification of the exit dose in radiotherapy treatment. The intended use of the OPTIVUE 1000ST is to provide patient positioning reference data and remains the same as the OPTIVUE (EPID) previously cleared in the ONCOR Avant-Garde product (K031764).

Additionally, the ONCOR Expression includes as standard an 82 leaf multi-leaf collimator that is marketed as OPTIFOCUS. The intended use of the OPTIFOCUS is unchanged from the previously cleared 82 leaf MLC in the ONCOR Avant-Garde product (K031764).

The COHERENCE Therapist Workspace with Release 2 and MVision is included with the ONCOR Expression system (is optional for the existing ONCOR and PRIMUS family of systems) and is based on the previously cleared COHERENCE Therapist workspace (K031764) utilizing more recently cleared *syngo* features (K040970) such as image post-processing, viewing, and display applications. The MVision application supports the Megavoltage Cone Beam acquisition method, which is used in conjunction with the OPTIVUE 1000ST flat panel, to obtain two dimensional projection images that serve the purpose of patient positioning reference data as cited above. The intended use of the COHERENCE Therapist Workspace remains unchanged.

As part of the MVision feature, the 3D reconstruction software application was previously cleared in the Siemens Siremobile Iso-C 3D C-Arm product (K040347). The intended use of the 3D imaging option allows the reconstruction of two-dimensional projection images acquired from an X-Ray source, (in this case a linear accelerator instead of an X-Ray C-Arm), into three-dimensional data where the physician benefits from the 3D information of high contrast objects and anatomical structures. The intended use of the 3D image reconstruction application remains unchanged from the predicate device.

Also as part of the MVision feature, the Adaptive Targeting application enhances the utilization of patient position localization data derived from the Megavoltage Cone Beam imaging application or imported from another 3D imaging system (i.e. CT or C-Arm system). The Adaptive Targeting application can automatically align the MVCB 3D reconstructed data with the 3D planning data using the calibrated machine isocenter and calculate any position offsets. The offset amount can be transferred to the treatment table to align the patient's setup position. The image alignment and offset calculation can be performed using both manual and automated tools. Adaptive Targeting is intended to provide a method by which the physician can improve treatment positioning accuracy in conventional fractionated radiation therapy.

The intended use of the ONCOR Expression with COHERENCE Workspaces remains unchanged from the predicate ONCOR Avant-Garde (K031764) and PRIMUS (K993425) medical linear accelerator systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
Siemens Medical Solutions, USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
CONCORD CA 94520

Re: K060226
Trade/Device Name: ONCOR Expression with COHERENCE™ Workspaces
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 26, 2006
Received: January 30, 2006

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

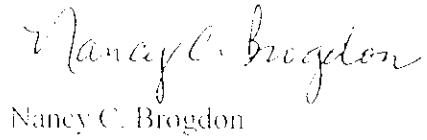
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indication For Use Statement

510(k) Number (if known): K060226

Device Name: ONCOR Expression with COHERENCE™ Workspaces

Indications for Use:

The intended use of the ONCOR Expression™ linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer.

The ONCOR Expression includes an Electronic Portal Imaging Device (EPID) that will be marketed as OPTIVUE™ 1000ST. The indications for use for the OPTIVUE 1000ST is the acquisition of portal images for the purpose of verification of the treatment field and shielding blocks in relation to patient positioning markers and/or anatomical landmarks in radiotherapy treatment. OPTIVUE 1000ST will also allow for verification of the exit dose in radiotherapy treatment. The indications for use remain unchanged from the previously cleared OPTIVUE EPID (K031764).

Additionally, the ONCOR Expression includes as a standard feature, an 82 leaf multi-leaf collimator that is marketed as OPTIFOCUS™. The OPTIFOCUS MLC is provided to assist the radiation oncologist in the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. The indications for use of the OPTIFOCUS MLC remains unchanged from the previously cleared OPTIFOCUS MLC (K031764).

The COHERENCE™ Workspaces:
The COHERENCE Therapist workspace includes a number of *syngo*™ based software applications who's indication for use include the viewing, processing, filming, and archiving of medical images. The COHERENCE Therapist Workspace also permits patient data management, patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The Therapist Workspace in this release includes MVision™ which consists of the Megavoltage Cone Beam imaging method for acquiring 2D projection data that is reconstructed by the Cone Beam reconstruction method into 3D data for use by the Adaptive Targeting™ application for advanced treatment localization and patient positioning. Adaptive Targeting can also use 3D data imported from other devices. The indications for use for the COHERENCE Therapist workspace remains unchanged from the previously cleared COHERENCE Therapist workspace (K031764).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060226

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)